

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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MAR 17 2000

- . Mr. Grant Ramaley
8333 216th Street, Southeast
Woodinville, Washington 98072-8060

Dear Mr. Ramaley,

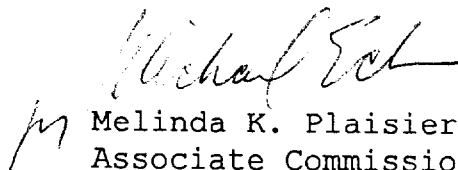
We are writing in response to Senator Slade Gorton's letter of January 24, 2000, on your behalf, concerning the medical device provisions of the FDA-European Union (EU) Mutual Recognition Agreement (MRA). Senator Gorton asked that we respond directly to you on the classification of medical devices described in the MRA, as you requested. The enclosed packet includes the medical device classification information you requested.

The Food and Drug Administration (FDA or the Agency) appreciates the time industry representatives take to voice their opinions on FDA matters. We welcome your comments and have forwarded them to the administrative file for this matter (docket 98S-1064). Your comments will be considered by Agency officials in their decision making process on this issue.

For your information we have also enclosed a copy of the Federal Register containing the classification information you requested, a Federal Register notice explaining the docket for the MRA, and other documents from FDA's website that you may find informative.

We trust that this information is helpful.

Sincerely,


Melinda K. Plaisier
Associate Commissioner
for Legislation

6 Enclosures

98S-1064

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cc: Dockets Management Branch, HFA 305
(Docket No.98S-1064)

The Honorable Slade Gorton
United States Senate
Washington, D.C. 20510-4701

SLADE GORTON
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January 24, 2000

Ms. Diane Prince
Office of Congressional Inquiries
Food and Drug Administration
U.S. Department of Health and Human Services
Parklawn Building
5600 Fishers Lane - Room 15 - 55
Rockville, MD 20857

Dear Ms. Prince:

I have been contacted by my constituent, Grant W. Ramaley, regarding the enclosed correspondence. Mr. Ramaley would appreciate information regarding the "Classification of Medical Devices" as described in the Mutual Recognition Agreement with the European Union. I am forwarding this information to you for your consideration.

I would appreciate you submitting his concerns to public docket 98S-1064 and looking into these questions about the Mutual Recognition Agreement. Please respond directly to Mr. Ramaley, and my Washington, D.C. office.

Thank you in advance for your attention to this matter.

Sincerely,



SLADE GORTON
United States Senator

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SG\law
Enclosures

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E-MAIL MESSAGE:

I have enlisted the help of Congressman Inslee to help investigate what is occurring within the FDA regarding the Mutual Recognition Agreement that is being formed between the European Union and The US.

Since my last request to you for help I have become even more concerned with the information I have obtained. Because I have not heard from you yet, I am going adapt my letter to Congress for your review. I know your very busy, I hope my concerns are worth you response. Please read the update letter to Congressman Inslee that follows, perhaps he can fill you in on what he has learned through his own investigation.

Dear Congressman Inslee,

December 14th 1999

Thank you for responding to my request. Please be fore-warned. I have been told by Wes Morgenstern at the FDA's office of compliance - Center for Device and Radiological Health (CDRH) that "the agency is sanitizing all responses to congressional inquiries regarding the MRA". I am very fortunate to have in my possession a letter from John Stigi - FDA Director, Division of Small Manufacturers Assistance, CDRH. He is the top FDA US representative working on the MRA. He is intelligent and has provided me (as of yesterday December 12th) a letter that identifies the progress and failings of the current MRA. His letter is well written and directly answers my questions point by point. Some of his remarks to my inquiries are quoted below.

Reminder - My concerns with the FDA is that there is no real substantial "agreement" occurring in the MRA. What I am suggesting is that the EU is telling the US what we will agree to and the FDA is merely agreeing. We are agreeing that FDA audits will not count for anything in Europe, even though the audit criteria is identical. The FDA has not been able to reach an agreement on classification of medical devices. These two most critical areas are all that matter in the agreement. Unless the US government stands its ground on these issues, prices will go up on medical devices and competition and innovation will slow down.

I will try and make this short: John Stigi writes - Section "Classification of Medical Devices" "We are more than aware of the differences in US and EU classification systems. Since country specific classification systems are not harmonized, there is nothing we can do to correct this problem."

John Stigis response to the EU not recognizing FDA audit determinations.

"There is currently no reciprocity for FDA inspections and NB [Notified Body]audits"

In John Stigis own words he points out that there is no agreement on classification of devices or who has authority to make determinations about compliance or noncompliance. The end result will be as if there is no agreement at all. In fact, the only MRA benefits that Mr. Stigi can suggest already occur without the "Agreement".

Why must congress get involved. The MRA has become a trade issue, not a health and safety issue. The FDA lacks the ability to negotiate a sensible agreement and has admitted this in no uncertain terms. I do not fault anyone at the FDA, the EU is committed itself to suffering under a huge regulatory burden and are trying to get other countries to commit to it as well. Without US cooperation, the EU will not be able to compete with the rest of the market since only its products will be burdened with costly implementation. We must not agree to it. We must point out its flaws and correct it.

There are many in the FDA who are not permitted to speak to congress and are being told to divert all inquiries to the "Agency". This alone suggests a cover-up. Contact Wes Morgestern at the FDA and don't give up until you speak with him directly. He has been specifically ordered to "put-off congressional inquiries" (his own words). He is allowed to tell the truth but not allowed to contact congress and tell them what he knows. I promised not to share some of what he told me. "only a congressional hearing will expose the whole truth" (his words). Remember this is a Deputy Division Director of the FDA speaking.

I would be careful to avoid the normal channels of communication. I was only able to speak to Mr. Morgenstern once, I reached him at 301.594.4699. I will also say this. I know that HIMA and the Dept of Commerce are involved. A representative from HIMA, warned me not to tell Congress. Why?

Grant Ramaley
Aseptico Inc.
Quality Assurance and Regulatory Affairs